UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,464	11/28/2006	Christoph Strassler	2084.5	6837

7590 07/29/2008

Hammer & Hanf
3125 Springbank Lane
Suite G
Charlotte, NC 28226

EXAMINER	
CHU, YONG LIANG	
ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
07/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,464	STRASSLER ET AL.	
	Examiner	Art Unit	
	YONG CHU	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,11 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-7, 11, and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/15/2006 and 05/06/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-7, 11, and 14 are pending in the instant application.

Information Disclosure Statement

Applicants' Information Disclosure Statements, filed on 06/15/17/2006, and 05/06/2008 have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

Priority

This application is a 371 of PCT/CH04/00374 filed on 06/18/2004, which claims the foreign priority of Switzerland patent application 1109/03, filed on 06/24/2003.

Response to Restriction

Applicants' election with traverse of Group I (claims 1, 3 and 4) in the reply dated on 05/06/2008 is acknowledged. Applicants have amended previously method claims 5-6 into a composition claims, and add new claim 14. Since there is no art rejection over the claimed product of claim 1, claims 1, 3-7, 11, and 14 will be examined together. Accordingly, the previous restriction requirement Office action dated 04/11/2008 among Group I, III, IV, and VI are hereby withdrawn.

Status of the Claims

Claims 1, 3-7, 11, and 14 will be examined on the merits.

Specification

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, 11, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, δ crystalline form of perindopril erbumine is characterized by the X-ray powder diffraction data. But the specification fails to describe the experimental conditions used for getting the X-ray diffraction data, such as CuKα irradiation energy, instrument brand name, the instrument calibration parameters, the sample size, and thickness of the sample for the experiment. All these factors would affect the X-ray diffraction data, which would affect the accuracy and precision of the cited X-ray diffraction data. The consistency of the operation condition is critical for the indexed peak numbers (or claim limitations), which the Office depends on for evaluating a claim's patentability over the prior art

teachings. The specification also fails to provide raw data of the X-ray powder diffraction spectrum of δ crystalline form of perindopril erbumin, because such spectrum demonstrates the quality of the X-ray diffraction data. Broadness of peaks in X-ray diffraction spectrum affects accuracy of the cited peak numbers. FDA characterizes the identity of a crystal requiring peak variation of angle 2 theta no more than 0.2 °C. If an X-ray diffraction spectrum is too broad, the peak number could be interpreted subjectively due to the variation, which could render a claim indefinite, and miss a prior art.

The specification also fails to provide TGA and DSC data to support the said crystalline is an anhydrate form, not a hydrate form. The claimed crystalline is recrystallized in a solvent containing water, it is possible the crystal is a hydrate. The specification needs to describe this to show the possession of the invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 3 claims the crystalline forms for use as therapeutic active substances. By definition, the term "therapeutic active substance" is defined as a substance used for treating any disease. The state of prior art shows such compound can be used as ACE inhibitor for treating hypertension, stable coronary artery disease, and heart failure, see *Wikipedia under Perindopril*, but

not any disease such as infection. Therefore, the scope of claim 3 is beyond the scope taught in the instant specification.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 6 claims a pharmaceutical composition for use in the treatment of cardiovascular diseases. According to WHO, the term "cardiovascular diseases" is defined as various diseases including rheumatic heart disease, congenital heart disease, etc. The state of prior art shows such compound can be used as ACE inhibitor for treating hypertension, stable coronary artery disease, and heart failure, see *Wikipedia under Perindopril*, but not disease such as rheumatic heart disease. Therefore, the scope of claim 3 is beyond the scope taught in the instant specification. Claim 6 is also rejected for failing to meet enablement requirement under 35 U.S.C. 112, first paragraph.

Claims 5-6, 11, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 5-6, 11, and 14 claims a pharmaceutical composition comprising the δ crystalline form of perindopril erbumin of claim 1. According to

a process for preparing a pharmaceutical composition disclosed in U.S. Patent publication *US2007/0178166* at paragraph [0041]-[0042], in order to mix a pharmaceutical with excipients, it is necessary to dissolve a pharmaceutical compound with excipients in a solution, and remove the solvent to make dry powder. During this formulation process, the claimed crystal will disappear. The instant specification fails to teach a process to make a pharmaceutical composition comprising the δ crystalline form of perindopril erbumin during the formulation without dissolving said crystalline.

Claims 5-6, 11, and 14 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. As explained above, in order to mix a pharmaceutical with excipients, it is necessary to dissolve a pharmaceutical compound with excipients in a solution, and remove the solvent to make dry powder. During this formulation process, the claimed crystal will disappear, and the instant specification fails to teach a process to make a pharmaceutical composition comprising the δ crystalline form of perindopril erbumin during the formulation. Accordingly, the instant specification also fails to meet enablement requirement under 35 U.S.C. 112, first paragraph.

Conclusion

- Claims 1, 3-7, 11, and 14 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./
Patent Examiner
Art Unit 1626